

Whistleblower Exposes 3 Big Issues in Pfizer's Covid Vaccine Clinical Trials



Udumbara (<https://udumbara.net/profile/udumbara>) May 6, 2022 - 05:48

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On Nov. 2, 2021 British Medical Journal (BMJ) published an article that revealed three big issues in Pfizer's vaccine trial based on interview with a whistleblower.

The whistle blower, Brook Jackson, was a regional director of one of Pfizer's vaccine trial companies, Ventavia Research Group in Texas.

Beginning the fall of 2020, there were 153 institutes, including Ventavia, that assisted Pfizer's vaccine clinical trial. Per Ventavia's website, the company is the largest private clinical research company in Texas. Jackson found out the management of the clinical trial in the company was not organized. She reported this to the

administrative level of the company, but received no response from the company. Then she reported this to the FDA.

However, after she emailed the FDA, she was fired that same afternoon. Jackson said this was the first time she was fired from her job in her 20-year career.

Finally, she contacted the international well-known journal-BMJ. She exposed 3 major issues she observed in Ventavia for Pfizer's vaccine clinical trial.

1. Falsifying the data
2. Early unblinding of the trial, affecting the accuracy of the results
3. Very slow to respond to adverse events, and not paying attention to the safety of participants

We spoke with Dr. Sean Lin, PhD, former toxicology lab director of Walter Reed Military Medical Center to discuss these issues. The interview below has been edited for brevity and clarity.

Issue 1: During the Trials, There Was Data Falsified

Health 1+1: Per Jackson, in one document dated as August 2020, before Jackson's hiring, a Ventavia executive revealed that three site staff members were requested to go over e-diary issues and falsifying data, etc. One of them was verbally questioned for changing data and not informing the late data entry.

Jackson and Ventavia executives discussed multiple times the possibilities of an FDA inspection of their company. Another former Ventavia employee also stated that the company worried the FDA would audit the process of their company's Pfizer's vaccine clinical trials.

Dr. Lin: When any new vaccine or new medication goes through clinical trials, the accuracy of the data is very important.

For example, in clinical trials, to inject vaccine to a volunteer, there must be 2 people in addition to the volunteer on site. One person does the injection; the second person takes notes and watches the injection. The reason for having two people is if only one person does it, if there is any mistake in recording the procedure, or if the person changes data, the accuracy of the database will be affected significantly.

In cases where any data needs to be modified, these drug companies usually have strict procedures. First, upper management and an executive of the drug company need to be notified and approve, then the person is authorized to enter the database and modify the data. The person must record the time of modification and

the reason. They need to explain that an error occurred while entering the data, or if there are other reasons. Only with strict rules can these companies guarantee that what is in the database won't be falsified.

So by contrast, it is unbelievable that an employee at Ventavia can have the right to modify the database without permission. This can cause big problems.

Pfizer published their clinical trial report on NEJM (New England Journal of Medicine). In the report, there were 8 people infected COVID after vaccination, but there were 162 people infected COVID after placebo. So, it is easily to change the protection rate from 90% to 60% if there are wrong data on dozens of people.

Ventavia's trial site had 1,000 volunteers participate in the COVID vaccine trials. If there are mistakes in just 50 of them, the results will be significantly different.

Issue 2: Early Unblinding of Trial Participants

Health 1+1: Based on the photos and information provided by Jackson, documents related to the clinical trials were randomly displayed, including vaccine packaging materials with clinical trial participants' information and drug assignment confirmation labels, all these were accessible to blinded personnel. The above errors can lead the participants and the staff members to know ahead of time who would get vaccine, before the procedures were done. The errors were corrected two months after the trial started. It may have been a large range of unblinding.

Dr. Lin: Generally, people who participate in clinical trials are divided into two groups. One group would receive vaccine and the other group would receive placebo, like normal saline. None of the participants will know which they were given, otherwise it would affect the objectivity of the trial. This is called blinding.

Vaccine trials routinely use blind trials. This is because in medical field, it is well known that the mental effect plays a key role. For example, if someone knew he or she was given real medicine, they may have very positive mood which improves their immune system, and the results would not truly reflect the effect of medicine only. On the other hand, if people knew they were given placebo, they may not feel any hope, and that may also affect the results.

Besides the volunteer participants, other people who involved in the trials like physicians, nurses, and people who man database are also not allowed to know the true information regarding the distribution of the vaccine injection. This is to avoid bias. For example, if the nurse knew the participants receiving vaccine, the nurse may pay more attention to the person. This will affect the end results.

So the clinical trials are randomly assigned by computer for who receives the vaccine and who receives the placebo, and the information will be encrypted.

For early unblinding, it was not only a lapse in responsibility on Ventavia's part, but showed problems related to Pfizer's design and management of these COVID vaccine clinical trials. This made it so that the testing groups learned who was getting the vaccine too early. If lower level staff have authority or opportunity to unblind trials, it affects the objectivity of the data.

Issue 3: Slow Response to Adverse Events, Not Prioritizing Participant Safety

Health 1+1: Jackson pointed out that Ventavia did not pay attention to the safety of the participants during the vaccine trials. They did not contact or take care the participants who developed side effects. One email sent by the contract research organization to Ventavia mentioned that over 100 cases with issues where participants were not contacted for more than three days, including including two participants who had developed severe symptoms. The expectation for vaccine trials is that that all issues need to be addressed within 24 hours. Jackson also mentioned that participants were placed in a hallway after injection with no clinical staff observation.

Besides Jackson, a formal Ventavia employee also told the BMJ that the company doesn't have enough staff to take samples from participants who developed COVID symptoms. FDA documents showed that across all clinical trials, there were 477 people who had symptoms but did not receive a PCR test for COVID. Jackson said in the 40-plus clinical trials she's been involved with, including several large scale trials, she had never seen as much chaos as the environment she worked in under Ventavia.

In a recording of a meeting in September 2020 between Jackson and two Ventavia company directors, the company expressed they could not confirm how many types of issues had occurred because of the high volume of issues, nor could they confirm the number of errors that had occurred because there was something new everyday.

Dr. Lin: In clinical trials, the risk of the medication given to participants is unknown, and as such there needs to be enough staff to watch for side effects that could occur.

Usually, participants stay onsite, whether that is a hospital or nearby hotel, for the first 24 hours after the vaccine injection, and they are accompanied by clinical staff. If a severe side effect occurs, it needs to be addressed right away. It is dangerous if no one is observing the participants after injection. This suggests the trial was not properly staffed.

In the past, there were clinical trials for certain medications that took a very long time before they could even begin. First you need to have enough test sites, then the standard data criterion needs to be set up to ensure the data integrity and security, among other things. If you have contractors with the capacity to test 500

people, but you sign them for contracts to test 1000 people, obviously they will have staffing and staff training issues. There's a standard protocol that accompanies each step of these clinical trials and no short cuts can be taken, even if a pharmaceutical company wants to speed up the testing period. In this case specifically, Pfizer would have needed to monitor these testing sites, in order to ensure all these trials are using their designed process.

Ventavia's situation implies additional risks, like the possibility of other sites having similar issues, and whether Pfizer has been correcting these in a timely manner. If the vaccine data contains errors, then wouldn't the vaccine's protection rate need to be reevaluated?

During the pandemic, many large pharmaceutical companies received protection from government. The entire vaccine development bill was footed by the government, as was the production and promotion costs. And even if there were problems in the process, the media was not investigating these steps and exposing the details to the public.

Pfizer's vaccine has been so important in the US market and stricter monitoring should have been in place, rather than blanket protections.

FDA's Poor Oversight

Health 1+1: Jackson reported the issue to the administrative level of Ventavia and received no response. Then on Sept. 25, 2020, she contacted the FDA. After sending the email, she was fired from the company. A few days later, the FDA contacted Jackson to discuss her report. There was no further communication between Jackson and the FDA after this call. In August 2021, the FDA approved Pfizer's COVID vaccine and listed 9 of the 153 clinical trial sites, not including Ventavia.

Jackson raised several problems in her report:

- 1) Participants were not monitored after receiving injections
- 2) There was no timely follow-up of patients with adverse side effects
- 3) Errors occurred during testing, and people would not report the errors
- 4) The vaccines were not stored at proper temperatures
- 5) Mislabeled laboratory specimens
- 6) Staff who reported these types of problems received retaliation
- 7) FDA told her no further information could be provided to her and ceased communications, and only nine of 153 test sites were inspected by the FDA, not including Ventavia, despite Jackson's report

This exposes the oversight issues on the FDA's part. In Ventavia case, FDA should have communicated with Jackson, Pfizer, and Ventavia. It stands that the FDA should have inquired about Pfizer's trial procedures, and whether these three parties were on the same page regarding those procedures. And the public should have been made aware, because this affects human lives.

Dr. Lin: It's more than an issue of corporate liability, there's a matter of individual responsibility here as well. This whistleblower's report showed that it wasn't just Ventavia in the wrong, but Pfizer and the FDA as well. But I think the key issue is still the individual, because you have to remember that these are individuals doing all the research.

Many people think that science is noble, and all the people who work in the scientific field are pursuing truth. But in reality, in modern society, science is an industry. Especially the medical field, it's become a large industry that involves huge profits. So in the process, the issue of how to keep research and clinical trials reliable and trustworthy has become a big challenge.

During the pandemic, the public had hope that pharmaceutical companies would develop medicine that could save lives. There's a big profit opportunity here for the companies, especially because the government will help cover costs and also promote the products. With an upside this big, no company wants to miss out. With these conditions, it's easy to risk the integrity of the company. Especially under the current PREP regulations, the company doesn't take any responsibility. Pfizer and Moderna are free of responsibility involving this vaccine. People with adverse side effects from these injects can seek compensation through CACP, but it is not easy to do.

According to a Nov. 10, 2021 report from USA Today, 3,100 people developed side effects after vaccine injection during clinical trials. Following the CACP system, they filed for reimbursement, and none of them have thus far received compensation.

The government pays for production and protection, and the companies don't need to pay out any losses from side effects. Big profits with small investments. Under these conditions how can one guarantee the integrity of the test? It in fact motivates the companies to rush their clinical trials. These are complicated procedures with many factors that can cause issues. Pharmaceutical companies should be following the basic principle of "do no harm." Without this principle, the medical field is in peril.

Both the government and pharmaceutical companies have been focusing on the benefit rather than the drawbacks. This is a problem, because it means that something that could put someone's life at risk can be ignored. This is irresponsible to the public.

On one hand, during a pandemic, ordinary people would of course wish that medical companies could develop medicine to save the world. Can pharmaceutical companies keep a high level of integrity through the process? I think this is a test for humanity arranged by God.

If humanity handles this test well, God creates miracles to help humanity.

If, under what is deemed an emergency condition, in the name of saving people at large a government decides to risk some people's lives in trade, that is not right. Just like in China, the regime is behind the operation of organ harvesting ordinary citizens to make a profit. If a surgeon in China claims he saved a life through organ transplantation but had to kill another human being to do so, that is totally wrong.

Whether a physician or pharmaceutical expert, whether you can maintain morality and integrity during this pandemic is a test from God. As COVID spread across the entire world, it's become a test not only to the medical field but all human beings.

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